K031700

AUG 2 9 2003

APPENDIX II

510(k) Summary

Medtronic Resting Heart System

(As required by 21CFR 807.92)

A. Submitter Information

Submitter's Name:	Medtronic Perfusion Systems
Address:	7611 Northland Drive N
	Minneapolis, Minnesota 55428-1088 U.S.A.
Telephone Number:	763.391.9000
Contact Person:	Preeti Jain
Date Submission Prepared:	May 30, 2003

B. Device Information

Device Trade Name:	Medtronic Resting Heart System
Common or usual Name:	Cardiopulmonary Bypass Surgery Circuit with Active Air Removal, Oxygenator, Centrifugal blood Pump, Arterial Filter, flow probe, tri-optic measurement cell, tubings and connectors, holding bag.
Classification Name:	**For the new/changed components:** Cardiopulmonary bypass blood reservoir, Cardiopulmonary bypass adaptors, fittings, manifold, **For the unchanged components:** Cardiopulmonary Bypass Oxygenator, Cardiopulmonary bypass heat exchanger, Cardiopulmonary Bypass blood pump (Non Roller type), Cardiopulmonary bypass arterial line blood filter, Cardiopulmonary bypass tubing, Cardiopulmonary bypass inline gas sensor, Cardiopulmonary bypass pump speed control

Predicate Devices(For new/changed components):

1. AFFINITY® Venous Reservoir Bag (K935717)
2. Carmeda™ Coated Tubings and Connectors (K891687)
3. Medtronic Overpressure/Vacuum Relief Valve (K953564)
4. CardioVentions CORx System (K012325)

Device Description:

The Medtronic Resting Heart System is a low prime volume alternative to existing Cardiopulmonary Bypass (CPB) perfusion circuit. The system is used for patient support during cardiopulmonary procedures lasting up to 6 hours. The System consists of the Medtronic Resting Heart System Controller for Active Air Removal and the Medtronic Resting Heart Disposable Module

The venous return portion of the CPB circuit is connected to a Venous Air Removal Device (VARD) that is equipped with an automated air removal system connected to the vent port on the device. The VARD is an AFFINITY Arterial Filter (38 micron) moved to the venous side of the circuit and equipped with ultrasonic crystals that sense the liquid level in the filter. The VARD replaces the Affinity™ Cardiotomy Venous Reservoir (CVR) or the Affinity™ Venous Reservoir Bag (VRB) that is normally used to remove air from the venous blood entering the CPB circuit.

Indications for Use:

The **Medtronic Resting Heart System** is intended for use in surgical procedures requiring extracorporeal gas exchange, circulatory support, and thermal regulation. This device is indicated for use in procedures requiring blood flow rate of 1 to 6 liters/min and lasting up to six hours. The system is indicated for use only with the Bio-Console.

C. Comparison of Required Technological Characteristics

Medtronic Resting Heart System is a system comprised of standard components of an extracorporeal circuit for use during cardiopulmonary bypass. The system has the same technological characteristics as a traditional circuit and the single components have the same technological characteristics as the predicate.

D. Performance Data

Performance data, such as, Air Handling capabilities, blood trauma, pressure drops have been provided in the 510(k) submission to show equivalence of the Medtronic Resting Heart System to a standard extracorporeal circuit. In addition comprehensive testing has been completed on the Active Air Removal Controller including performance and Software Verification and Validation.

Conclusion

Medtronic Resting Heart System is substantially equivalent to the noted predicate device based on the similarities of technological characteristics, indications for use and the results of performance comparative testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Medtronic Perfusion Systems
c/o Ms. Preeti Jain
7611 Northland Drive
Minneapolis, MN 55428

Re: K031700
Medtronic Resting Heart™ System
Regulation Number: 21 CFR 870.4290, 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir and Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (two)
Product Code: DTN, DTL
Dated: May 30, 2003
Received: June 2, 2003

Dear Ms. Jain:

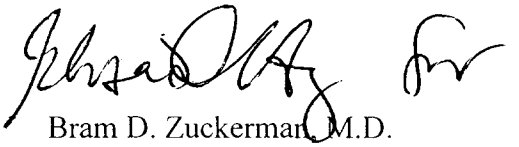
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX IV

Indications for Use Statement

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510(k) Number (if known): K031700

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031700

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Prescription Use X
(Per 21 CFR 801.109)